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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/130,887 08/07/98 GOLD

B 899-50283

EXAMINER

LEE, L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

05/15/00

HM12/0515
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/130,887

Applicant(s)

Gold

Examiner

LI Lee

Group Art Unit

1645



☒ Responsive to communication(s) filed on Feb 29, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-20 is/are pending in the application

Of the above, claim(s) 1-5, 12, and 14-20 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 6-11 and 13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's amendment filed on Feb 29, 2000 (Paper Number 8) has been received and entered. Claim 6 has been amended, and new claims 7-20 have been added, consequently claims 1-20 are pending in the instant application.

Newly submitted claim 12 is a second method of identifying a non-binding FK506 analog, which has different steps and uses different reagents from the method of Group II. Claim 12 would have been set forth as a patentably distinct invention (Group III) had it been presented earlier. Further claims 14-20 would also have been a patentably distinct invention (Group IV) because claims 14-20 are drawn to a method of identifying a FK506 analog that stimulates nerve cell growth which is independent or distinct method from the methods in Group II and Group III, since the method of Group IV has a different objective, recites different steps, and do not necessarily result in the same products. Since applicant has received an action on the merits for the originally presented invention (Group II, claim 6), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12 and 14-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The rejection of claim 6 under 35 U.S.C. 102(a) as being anticipated by Steriner et al (Nature Medicine 3(4):421-428, April 1997) is maintained and applied to the newly added claims 7-11 and 13 for reasons made of record in Paper No 8, mailed on 11/09/99.

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Applicant's are asserting that the method of identifying a non-binding FK506 analog of Steriner et al does not have exactly steps of the claimed invention (e.g., selecting a FK506 analog that has poor binding affinity to FKBP-12). However, the method of Steriner et al identifies the same chemically, structurally, and biologically compositions with the steps as the claimed invention (e.g., screen a plurality of FK506 analogs (more than one analogs have been screened, Table 1) for binding to FKBP-12, the screened analogs have the same structures as the instant claimed invention, and the screened analogs have the same biological activity of the claimed invention, in promoting nerve cell growth). While Steriner does not use the words "screening" and "selecting" per se, the identifying of non-FK506 analogs which have different binding affinities to FKBP-12 (Table 1) require that Steriner possesses a plurality of FK506 analogs which Steriner tests or screens for binding to FKBP-12 and then identifies or selects for non-binding activity. Accordingly, Steriner anticipated the claimed invention. As further evidence, Applicant should note that the method of Steriner identified the same FK506 analogs as disclosed in the instant application and thus Steriner does teach away from the claimed invention. Moreover, the FK506 analogs of Steriner have same K_d binding values cited in the claims, which are encompassed by the binding activity disclosed in Table 1. Therefore, the claimed invention is anticipated by the prior art.

New Grounds of Rejections Based on the Applicant's Amendment

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Claim Rejections - 35 USC § 112

3. Claims 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the agent" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

The term "substantially" in claim 11 is a relative term which renders the claim indefinite. The term "substantially inhibit" is not defined by the claim and encompass low, medium and high inhibition, the specification does not provide a standard for ascertaining the requisite degree of the inhibition, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

4. Claims 6-11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Steriner et al (US 5,801,197, Sep 1, 1998).

Steriner et al teach a method of identifying a non-binding FK506 analog (column 7) which has the same structure as recited in the instant claim 13 (see columns 7-14). Steriner et al also teach that the non-binding FK506 analogs have different FKBP-12 binding affinities or potencies of inhibition of the rotamase activity (column 9, K1 Test Procedure, and Tables I and IV) and stimulation of nerve cell growth (columns 11-12).

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5. Claims 6-11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Armistead (US 6,037,370, Mar 14, 2000).

Armistead teaches a method of identifying a non-binding FK506 analog (columns 2-8) which has the same structure as recited in claim 13. Armistead also teaches screening a plurality of FK506 analogs with different FKBP-12 binding affinities from 0.1- > 500 or potencies of inhibition of the rotamase activity (column 12, FKBP-12 binding assay and Table 1a). The non-binding FK506 analogs of Armistead are capable of stimulating nerve cell growth (Examples 2-3).

Status of Claims

6. No claims are allowed. All claims stand rejected.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee
May 11, 2000


PHUONG T. BUI
PATENT EXAMINER